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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/965,610
Filing Date: September 26, 2001
Appellant(s): CANTOR ET AL.

DOROTHY P. WHELAN
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 30, 2010 appealing from the Office action mailed March 25, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-9, 16-18, 28, 29, 35, 36 and 39-103 are pending.

Claims 48-51 and 55-91 are withdrawn.

Claims 1-9,16-18, 28, 29, 35, 36, 39-47, 52-54 and 92-103 are currently appealed.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 5,474,783	Miranda et al.	12-1995
WO 96/08229	Garbe et al.	03-1996

(9) Grounds of Rejection

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following ground(s) of rejection are applicable to the appealed claims:

A. Claim Rejections - 35 USC § 102

Claims 1-5, 35, 39-42, 52, 53, 92-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Miranda et al. (US 5,474,783, provided in IDS filed 09/26/2001).

The present independent claims 1, 35, 92, 95 are directed to a transdermal drug delivery composition comprising: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; wherein the composition is free of undissolved fentanyl. The claimed component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof, is an optional component.

Miranda disclosed transdermal drug delivery device that permits selectable loading of drug into dermal formulation and adjustment of delivery rate the drug from the composition through the dermis, while maintaining acceptable shear, tack, and peel adhesive properties (abstract). The drug can be loaded in the dermal formulation from 0.3-50% (col.8, line 65-col.9, line 8). The dermal formulation comprises up to 96% polyacrylate copolymers (col.4, lines 6-12). The polyacrylate copolymer comprises alkyl acrylate monomer including isooctyl acrylate copolymerized with monomer having

functional groups including hydroxyethyl acrylate (col.9, lines 21-59). One of the preferred drug to be delivered by this transdermal device is fentanyl as evident by claim 27 of the reference. The reference does not teach undissolved drug in the system, i.e. free from undissolved fentanyl. The reference disclosed transdermal device comprising backing layer and release liner (figure 1). The dermal formulation comprises permeation enhancer in a concentration up to 20% and includes isopropyl myristate, and glycols (col.13, lines 5-24; col.14, lines 5-10). The reference teaches the dermal formulation is adhesive and is adhered to a backing layer (col.4, lines 29-35; figures).

B. Claim Rejections - 35 USC § 103

Claims 1-9, 16-18, 28-29, 35-36, 39-47, 52-54 and 92-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al. (US 5,474,783) in view of Garbe et al. (WO 96/08229), both references are of record.

Applicant Claims

The present independent claims are directed to a transdermal drug delivery composition comprising: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; wherein the composition is free of undissolved fentanyl. The

claimed component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof, is an optional component.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Miranda teaches transdermal drug delivery device that permits selectable loading of drug into dermal formulation and adjustment of delivery rate the drug from the composition through the dermis, while maintaining acceptable shear, tack, and peel adhesive properties (abstract). The drug can be loaded in the dermal formulation from 0.3-50% (col.8, line 65-col.9, line 8). The dermal formulation comprises up to 96% polyacrylate copolymers (col.4, lines 6-12). The polyacrylate copolymer comprises alkyl acrylate monomer including isooctyl acrylate copolymerized with monomer having functional groups including hydroxyethyl acrylate (col.9, lines 21-59). One of the preferred drug to be delivered by this transdermal device is fentanyl as evident by claim 27 of the reference. The reference does not teach undissolved drug in the system, i.e. free from undissolved fentanyl. The reference disclosed transdermal device comprising backing layer and release liner (figure 1). The dermal formulation comprises permeation enhancer in a concentration up to 20% and includes isopropyl myristate, and glycols (col.13, lines 5-24; col.14, lines 5-10). The reference teaches the dermal formulation is adhesive and is adhered to a backing layer (col.4, lines 29-35; figures).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Miranda teaches copolymers of functional and non-functional monomers to form the polyacrylate of the dermal formulation, however, the reference does not exemplify the copolymer. Miranda further does not teach macromonomer as claimed by claims 7-9, 98, or ratios of monomers and macromonomers in the copolymer as claimed by claims 6, 17, 18, 36, and 98. Miranda does not teach the specific enhancers as claimed by claims 43-47, 102.

The missing elements from Miranda were all taught by Garbe, as well as the claimed copolymer without polysiloxane.

Garbe teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (page 2, lines 5-23). The copolymer comprises 40-90% of one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group and up to 60% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomers. The composition further comprises more than 30% of a macromonomer copolymerizable with the A and B monomers (page 2, lines 5-23). The A monomers are taught on page 4, lines 3-14 with isooctyl acrylate preferred. The B monomers are taught on page 4, line 15 through page 5, line 12, with hydroxyethyl acrylate preferred. The macromonomers are taught on page 5, line 13 through page 8, line 28. Polymethylmethacrylate macromonomers are preferred (page 6, lines 17-18). Example of page 19 teaches copolymer comprising 55% isooctyl acrylate, 40% hydroxyethyl

acrylate and 5% polymethylmethacrylate, as claimed by applicants. The softeners of the delivery device affect skin penetration rate and include fatty acids, fatty alcohols, fatty acid esters such as methyl laurate and tetraglycols (page 8, line 29 - page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (page 10, lines 7-15). Garbe further contemplates various drugs for delivery by the device including analgesics such as fentanyl (page 12, line 28). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (page 13, line 18-20). The transdermal device comprising the pressure sensitive adhesive taught by Garbe allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with skin, and can be removed cleanly from the skin (page 3, lines 11-15).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal composition to deliver fentanyl wherein the composition comprises a copolymer comprising monomers selected from the group consisting of alkyl acrylates and alkyl methacrylates; and unsaturated monomers; and about 0.3% to about 50% by weight fentanyl; wherein the composition is free of undissolved fentanyl and further comprising permeation enhancer as taught by Miranda, and further select copolymer having 55% isooctyl acrylate, 40% hydroxyethyl acrylate

and 5% polymethylmethacrylate, without polysiloxane, as taught by Garbe, and replace the permeation enhancer with enhancer selected from tetraglycol and methyl laurate as taught by Garbe. One would have been motivated to do so because Garbe teaches that transdermal device comprising such copolymer made of functional and non-functional monomers and macromonomers in specific ratios, and further comprises permeation enhancer allows dissolution of drug and provides matrix that is substantially free of solid undissolved drug, and further the copolymer maintains contact with skin, and can be removed cleanly from the skin. One would reasonably expect formulating transdermal composition to deliver fentanyl comprising copolymer comprising 55% isooctyl acrylate, 40% hydroxyethyl acrylate, 5% polymethylmethacrylate and the composition further containing enhancer selected from tetraglycol and methyl laurate wherein the composition allows dissolution of fentanyl and is free of undissolved fentanyl, and meanwhile the composition has good skin contact adhesion and cleanly removed from the skin. The polymer composition taught by the combination of Miranda and Garbe does not necessarily contain polysiloxane.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

(10) Response to Argument

A. Appellants argue that Miranda does not anticipate claims 1-5, 35, 39-42, 52-53, and 91-97 because the claims exclude Miranda's polysiloxane

Claims 1-5, 35, 39-42, 52-53, and 91-97 are directed towards transdermal drug delivery compositions for delivering fentanyl "consisting essentially of" an acrylate copolymer, fentanyl, and, in some cases, certain specified ingredients (adjuvants, plasticizers, and tackifiers). Miranda clearly teaches adding an amount of polysiloxane to the polyacrylate that is specifically designed to affect the transdermal drug delivery properties of the composition. Miranda criticizes compositions that include only a single adhesive polymer, and states that the second adhesive polymer modulates the release of the drug from the adhesive composition.

In response to this argument, it is argued that component (a) of the claimed composition that recites the polymer part of the composition is not closed language, and includes the expression "comprising" that permits other polymers including polysiloxanes. The expression **“consisting essentially of” in the preamble** of the claim limits the scope of the claim to the three specified ingredients/components (a), (b) and (c), however, ingredient (a) is broadened by the expression “comprising” and is not limited. The transitional term **"comprising"**, which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.,* 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."). *Invitrogen Corp. v. Biocrest Mfg.*, L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003)

("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.,* 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). *In Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005).

In any event, the expression “consisting essentially of” limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference’s composition are excluded by the recitation of “consisting essentially of”, applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant’s composition. *In re De Lajarte,* 337 F 2d 870, 143 USPQ 256 (CCPA 1964). **Applicants disclosed in their specification, page 7, lines 20-25, that polysiloxanes are suitable pressure sensitive adhesive for their invention. Nothing of record shows that polysiloxanes have detrimental effect on the acrylate polymer of the invention.** Further, it has been held that omission of an

element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

Appellants argue that “consisting essentially of” limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition." In this case, the listed ingredients are an acrylate copolymer, fentanyl, and, in some cases, certain specified ingredients (adjuvants, plasticizers, and tackifiers). The "basic and novel characteristics" of this composition relate to the transdermal delivery of fentanyl. Accordingly, the issue with respect to Miranda is whether the "consisting essentially of" language in the claims excludes Miranda's polysiloxanes. An ingredient may "affect" the transdermal drug delivery properties of the composition either positively or negatively. The "consisting essentially of" language does not exclude ingredients that detrimentally affect the transdermal drug delivery properties of the composition. The Examiner's position is that the "consisting essentially of" language in Appellants' claims does not exclude Miranda's polysiloxanes, presumably because there is no evidence that inclusion of the polysiloxanes detrimentally affects the properties of the claimed transdermal drug delivery compositions. Miranda itself belies the Examiner's position. The entire reason Miranda includes the polysiloxanes is to affect the drug delivery characteristics of the composition.

In response to this argument, it is argued that Miranda teaches polysiloxane in an amount that can be as low as 4%. In absence of definition of the expression “consisting essentially of” by appellants, the amount taught by Miranda can fall within the ingredients covered by the expression “consisting essentially of". As appellants themselves admit, polysiloxane taught by Miranda to affect the drug delivery properties and according to the desired drug delivery property, the polysiloxane can be diminished or increased according to the desired delivery characteristics. It has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

It has been held that "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries,* 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao,* 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, **absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."** See, e.g., *PPG,* 156 F.3d at 1355, 48 USPQ2d at 1355

("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac,* 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.); *In re Janakirama-Rao,* 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). **If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.** *In re De Lajarte,* 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman,* 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). Appellants have not shown in the specification that polysiloxane would change the characteristic of their invention.

Appellants argue that it is irrelevant that Appellants' specification discloses polysiloxanes because merely listing them says nothing about whether they affect the transdermal drug delivery characteristics of an acrylate-containing composition. The

only evidence of record on the issue of whether Miranda's polysiloxanes would affect the drug delivery properties of an acrylate-containing transdermal drug delivery composition is what Miranda says.

In response to this argument, the examiner is pointing to *In re Herz,* 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976), wherein (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. **In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention.** The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.).

It has been held that "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries,* 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao,* 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, **absent a clear indication in the specification or claims of what the basic and novel**

characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG,* 156 F.3d at 1355, 48 USPQ2d at 1355; *In re Janakirama-Rao,* 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). **If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.** *In re De Lajarte,* 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman,* 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). Appellants have not shown in the specification that polysiloxane would change the characteristic of their invention.

B. Appellants argue that the proposed combination of Miranda and Garbe does not render claims 1-9, 16-18, 28-29, 35-36, 39-47, 52-54, and 92-103 obvious

The Examiner's proposed combination of Miranda and Garbe for obviousness purposes is improper. The rejection is based upon the premise that because Garbe describes acrylate polymers without polysiloxanes, it would have been obvious to combine the teachings of the two references, while at the same time omitting Miranda's polysiloxanes. The Examiner's proposed combination ignores the fact that Miranda expressly teaches that the presence of the polysiloxane is critical. In this regard, it is irrelevant that Garbe's compositions lack the polysiloxane because one cannot use the absence of polysiloxanes in Garbe's composition as a license to ignore Miranda's plain

admonition that a transdermal drug delivery-altering amount of polysiloxane must be included.

In response to this argument, it is hereby repeated the response set forth in this examiner's answers regarding Miranda's reference. The claims' language and the present disclosure do not absolutely exclude polysiloxane of Miranda that is as low as 4%. Although Miranda anticipate the present claims and can stand by itself to render the claims obvious, however, Garbe shows that even 4% of polysiloxane of Miranda can be excluded from the polymer composition and may be replaced by macromer and still provide excellent drug dissolution. Garbe teaches that transdermal device comprising copolymer made of functional and non-functional monomers and macromonomers in specific ratios allows dissolution of drug and provides matrix that is substantially free of solid undissolved drug, and further the copolymer maintains contact with skin, and can be removed cleanly from the skin. From the combined teachings of Miranda that teaches 4% polysiloxane to modulate the drug solubility and Garbe that teaches polyacrylate copolymer combined with macromer can provide good dissolution to the extent of absence of undissolved drug and provide matrix that maintains good skin contact, one would reasonably expect formulating transdermal composition comprising copolymer comprising 55% isooctyl acrylate, 40% hydroxyethyl acrylate, 5% polymethylmethacrylate wherein the composition allows dissolution of drugs and is free of undissolved drugs, and meanwhile the composition has good skin contact adhesion and cleanly removed from the skin. The polymer composition taught by the combination of Miranda and Garbe does not necessarily contain polysiloxane. Therefore,

combination of the references is proper because it provides motivation to combine the references, and provides reasonable expectation to arrive to the present invention. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Appellants argue that the two references simply cannot be combined, or at the very least, cannot be combined to yield a composition that lacks Miranda's polysiloxanes, which Appellants' claims exclude. It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

In response to this argument it is argued that the references are combinable because both cited prior art reference are in the field of applicant's endeavor and both references are reasonably pertinent to the particular problem with which the applicant was concerned that is transdermal drug deliver. Both references are analogous art. It has been held that in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Further, as set forth in this examiner's answer, the claims' language, as well as the present disclosure, do not absolutely exclude polysiloxane. The Supreme Court stated in KSR, When there is motivation "to solve a problem and there are a finite number of

identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. This is the case here, only finite number of solution for drug transdermal delivery. The prior art recognized successful transdermal drug delivery achieved by acrylate copolymers with macromer as taught by Garbe, as well as successful transdermal drug achieved by acrylate copolymer and as little as 4% polysiloxane.

It has been held that “When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative

steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

Finally, a conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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/Sharmila Gollamudi Landau/
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